K130212

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date Prepared: Jan. 01.2013

1. Submitter Name and Address:

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NOV 2 0 2013

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2. Submission Devices Information:

Trade/Proprietary Name: Safty Hypodermic Needles With/Without Syringe.

Common Name: Hypodermic Needle and Piston Syringe

Classification name: Hypodermic Single Lumen Needle and Piston Syringe.

Class: II and II.

Panel: 80 and 80.

Procodes: FMI - Hypodermic Single Lumen Needle and FMF - Piston Syringe and FMI - Hypodermic Single Lumen Needle

3. Predicate Devices Information:

Safety Hypodermic Needle With/Without Syringe.
Trade Name: TERUMO® SurGuard®3 Safety Needle
510(K) Number: K113422
Trade Name: BD Single Use, Hypodermic Syringe

510(K) Number: K110771

4. Devices Description:

Safety Hypodermic Needle With/Without Syringe

The Safety Hypodermic Needle With/Without Syringe consists of a hypodermic needle with a hinged safety sheath attached to the connector hub with or without an attached hypodermic syringe. This device features a hinged safety sheath attached to the needle hub. The safety sheath which are simultaneously activated when manually pressed over the needle immediately after use and just prior to disposal to minimize the possibility of sharps injury. The safety sheath is activated with a one-handed operation by pressing the sheath either by finger or thumb, or by surface activation.

The locking mechanisms are positioned within the center and proximal end of the Sheath. The hinge feature allows the medical practitioner to flexibly adjust the sheath to its desired position for use.

Ref Number	Model Number	Description	Length	Gauge	Syringe
YSSN001	YSSN	Safety Hypodermic Needle	1/2 to 1"	30G	0.5 to 10cc
YSSN002	YSSN	Safety Hypodermic Needle	1/2 to 1"	29G	0.5 to 10cc
YSSN003	YSSN	Safety Hypodermic Needle	1/2 to 1"	28G	0.5 to 10cc
YSSN004	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	27G	0.5 to 10cc
YSSN005	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	26G	0.5 to 10cc
YSSN006	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	25G	0.5 to 10cc
YSSN007	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	24G	0.5 to 10cc
YSSN008	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	23G	0.5 to 10cc
YSSN009	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	22G	0.5 to 10cc
YSSN010	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	21G	0.5 to 10cc
YSSN011	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	20G	0.5 to 10cc
YSSN012	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	19G	0.5 to 10cc
YSSN013	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	18G	0.5 to 10cc
YSSN014	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	17G	0.5 to 10cc
YSSN015	YSSN	Safety Hypodermic Needle	1 to 1 1/2"	16G	0.5 to 10cc

5. Intended Use:

Safety Hypodermic Needle With/Without Syringe

The Safety Hypodermic Needle (With/Without Syringe) device is intended for use in the aspiration and injection of fluids for medical purposes. The Safety Hypodermic Needle (With/Without Syringe) is compatible for use with standard luer slip and luer lock syringes.

Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle-stick.

6. Technological Characteristics:

Through comparisons between the applicant devices with the predicate devices as follows tables. We believe the applicant devices are substantially equivalent with the predicate devices.

Safety Hypodermic Needle With Syringe Comparison Table

Element of Comparison	Submission Device	Predicate Device K113422
Intended Use	The hypodermic needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe.	The TERUMOO SurGuard®3 Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TERUMO SurGuard®3 Safety Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.
Principle of Operation	Normal	Normal
Needle Gauge and Length	Various Sizes	Various Sizes
Lubricant for Needle	Silicone Oil	Silicone Oil
Materials **Needle Hub** **Needle** **Needle Sheath**	 PP Stainless Steel PE	 PP Stainless Steel PE
Sharps Injury Prevention Features	Needle safety shield	Needle safety shield
Performances	Conforms to ISO7864	Conforms to ISO7864
Biocompatibility	Conforms to ISO10993	Conforms to ISO10993
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801

Element of Comparison	Submission Device	Predicate Device K110771
Intended Use	Sterile Piston Hypodermic Syringes (With/Without Needle) is a device intended for medical	The BD Single Use, Hypodermic Syringe is intended for use by health care

	purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body.	professionals for general purpose fluid aspiration/ injection.
Principle of Operation	Normal	Normal
Syringe Capacity	Various Sizes	Various Sizes
Nozzle Type	Luer	Luer
Lubricant for Barrel	Silicone Oil	Silicone Oil
Barrel Transparency	Transparent and Clear	Transparent and Clear
Gradations Legibility	Legible	Legible
Needle Gauge and Length	Various Sizes	Various Sizes
Lubricant for Needle	Silicone Oil	Silicone Oil
Materials		
Barrel	PP	PP
Plunger	PE	PE
Piston	Rubber	Rubber
Nozzle Cap	PE	PE
Needle Hub	PP	PP
Needle	Stainless Steel	Stainless Steel
Performances	Conforms to ISO7886-1	Conforms to ISO7886-1
Biocompatibility	Conforms to ISO10993	Conforms to ISO10993
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801

7. Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate device are substantially equivalent and are safe and effective for their intended use.The new device is safety.
Our device and the predicate device are same in intended use, Essential Component, Material, Sterile, Function etc.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 20, 2013

Wuxi Yushou Medical Appliances Company, Limited
C/O Garfield Wang
Regulatory Associate
215 No. Xigang Road
Dongbeitang Wuxi City
Jiangsu, China 21491

Re: K130212
Trade/Device Name: Safety Hypodermic Needles With/Without Syringe
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI/FMF
Dated: October 18, 2013
Received: October 21, 2013

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S

for

Erin Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device and
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130212

Device Name
Safety Hypodermic Needles With/Without Syringe

Indications for Use *(Describe)*
The Safety Hypodermic Needle With/Without Syringe device is intended for use in the aspiration and injection of fluids for medical purposes. The Safety Hypodermic Needle With/Without Syringe is compatible for use with standard luer slip and luer lock syringes.

Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle-stick.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by
Richard C. Chapman
Date: 2013.11.19
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